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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,595	04/16/2004	Mark A. Hoffman	CRNC	1203

46169 7590 09/07/2007
SHOOK, HARDY & BACON L.L.P.
Intellectual Property Department
2555 GRAND BOULEVARD
KANSAS CITY, MO 64108-2613

EXAMINER

SIMS, JASON M

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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09/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/826,595

Applicant(s)

HOFFMAN ET AL.

Examiner

Jason M. Sims

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-16, 18-24, 27-33, 35-41 and 44-50 is/are pending in the application.
- 4a) Of the above claim(s) 8, 9, 17, 25, 26, 34, 42 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-16, 18-24, 27-33, 35-41 and 44-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 June 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's arguments, filed 6/8/2007, have been fully considered but they are not deemed to be persuasive. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 6/8/2007, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Claims 1-7, 10-16, 18-24, 27-33, 35-41, and 44-50 are the current claims hereby under examination.

Drawings

The objection to the drawings filed 4/16/2007 has been withdrawn because of applicant's filing of new and corrected drawings filed 6/8/2007.

The drawings received on 6/8/2007 have been accepted and entered.

The following is a new rejection that has been necessitated by amendment.

Claim Rejections - 35 USC § 112 First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 28, and 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 11 contains the new matter of "dynamically accumulating" polymorphism values, which comprise the list. Support for the amended wording has not been found in the specification or specifically pointed to by applicant.

Claim Rejections - 35 USC § 112 Second Paragraph

Response to applicant's arguments:

Applicant's arguments, filed 6/8/2007, with respect to the claims 1, 18, and 35 as being rejected under 35 USC 112 second paragraph have been fully considered and are persuasive because of applicants amendments. Therefore, the rejection has been withdrawn.

Applicant's arguments, filed 6/8/2007, with respect to the claims 5, 22, and 39 as being rejected under 35 USC 112 second paragraph have been fully considered and are persuasive because of applicants amendments. Therefore, the rejection has been withdrawn.

Applicant's arguments, filed 6/8/2007, with respect to claim 10 as being rejected under 35 USC 112 second paragraph have been fully considered and are persuasive because of applicants amendments. Therefore, the rejection has been withdrawn.

Applicant's arguments, filed 6/8/2007, with respect to claims 27 and 44 as being rejected under 35 USC 112 second paragraph have been fully considered and are

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persuasive because of applicants amendments. Therefore the rejection has been withdrawn.

Applicant's arguments, filed 6/8/2007, with respect to claims 15, 32, and 49 as being rejected under 35 USC 112 second paragraph have been fully considered and are persuasive because of applicants amendments. Therefore the rejection has been withdrawn.

Applicant's arguments filed 6/8/2007 with respect to the rejection of claims 11-13, 28-30, and 45-47 have been fully considered but they are not persuasive.

Applicant only states that their amendments to the claims overcomes the indefiniteness rejection and are believed to be in condition for allowance.

The rejection of said claims has been stated below in the instant office action as the amendment has not overcome the prior indefinite and vague rejection.

Applicant's arguments filed 6/8/2007 with respect to the rejection of claim 14 has been fully considered but they are not persuasive.

Applicant only states that their amendments to the claims overcomes the indefiniteness rejection and are believed to be in condition for allowance.

The rejection of said claim has been stated below in the instant office action as the amendment has not overcome the prior indefinite and vague rejection.

Applicant's arguments filed 6/8/2007 with respect to the rejection of claims 31 and 48 have been fully considered but they are not persuasive.

Applicant only states that their amendments to the claims overcomes the indefiniteness rejection and are believed to be in condition for allowance.

The rejection of said claims has been stated below in the instant office action as the amendment has not overcome the prior indefinite and vague rejection.

The following rejections are either being reiterated or newly made and have been necessitated by amendment:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-7, 10-16, 18-24, 27-33, 35-41, and 44-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 18, and 35 contain the word "association" in when describing a relationship between polymorphism values and atypical clinical events. It is unclear as to what exactly the relationship is or the "association" is between polymorphism values and the atypical clinical events and with the clinical agent. It appears that the "association" may be either a direct or indirect association with the atypical clinical event or clinical agent. Therefore, the possibility of an indirect association between a value and the atypical clinical event and clinical agent is so broad as to not be reasonably interpretable to one of ordinary skill in the art and causes the step to be vague and indefinite. Clearer claim wording is required.

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Claim 11 contains the wording "dynamically accumulated," which is deemed as vague and indefinite. It is unclear as to what exactly the wording "dynamically accumulated" refers. Clearer claim wording is required.

Claim 12 recites the limitation "the second list" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Independent claim 1 only states a list, referring to a single list. It is unclear as to what previously stated second list claim 12 is referring.

Claims 14, 31, and 48 have been deemed as vague and indefinite. It is unclear as to what exactly the method step or component capable of carrying out the method step are referring. It is unclear as to how the step of querying a data structure, which apparently includes two data sets, but only at different times, results in the determining if a gene is associated with the clinical agent information. It appears that the data structure contains different data sets depending on the type of querying. It is equally confusing as to what exactly comprises the data structure. For instance, the data structure includes a data set, which is unclear as to what comprises the data set, and contains agent-gene associations. Additionally, the data structure, at a different point in time, comprises a second data set, which is unclear as to what exactly the data set contains, and contains polymorphism-atypical result associations. It is unclear as to what exactly is involved in the method step of claim 14. Clearer claim wording is required.

Claims 2-7, 13, 15-16, 19-24, 27-33, 36-41, 44-47, and 49-50 are rejected as being dependent from a rejected claim.

Claim Rejections - 35 USC § 103

Response to applicant's arguments:

Applicant's arguments filed 6/8/2007 have been fully considered but they are not persuasive.

Applicant argues that the specification contains limitations to the claims not found in the prior art reference, such as disclosing a computer system where the clinician may input clinical agent information by viewing "an expansive list of clinical agents, and selecting the desired agent by inputting [the name of] the desired agent."

Applicant's arguments are not found to be persuasive, as applicant's arguments are based on the attempt to read limitations found in the specification into the claims during claim interpretation. The stated limitations found in the specification are not read into the claim language during examination. The claims are to be read in light of the specification, which is very different than reading language from the specification into the claims as stated below and from the courts:

"415 F.3d at 1316, 75 USPQ2d at 1329. See also < In re Hyatt, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969) (Claim 9 was directed to a process of analyzing data generated by mass spectrographic analysis of a gas. The process

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comprised selecting the data to be analyzed by subjecting the data to a mathematical manipulation. The examiner made rejections under 35 U.S.C. 101 and 102. In the 35 U.S.C. 102 rejection, the examiner explained that the claim was anticipated by a mental process augmented by pencil and paper markings. The court agreed that the claim was not limited to using a machine to carry out the process since the claim did not explicitly set forth the machine. ***The court explained that "reading a claim in light of the specification, to thereby interpret limitations explicitly recited in the claim, is a quite different thing from reading limitations of the specification into a claim," to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have no express basis in the claim.*** The court found that applicant was advocating the latter, i.e., the impermissible importation of subject matter from the specification into the claim.). See also *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997) (The court held that the PTO is not required, in the course of prosecution, to interpret claims in applications in the same manner as a court would interpret claims in an infringement suit. Rather, the "PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification.").

Applicant further alleges that the Hogan reference fails to teach or fairly suggest receiving clinical agent information input by a clinician, where the clinical agent information includes identification of a specific clinical agent.

Applicant's allegations are not found persuasive as Hogan clearly shows and fairly suggests that the received genomic profile comprises clinical data, which inherently would be input by the clinician as in Fig. 2, subject data, and research data and is used by the M.D.. The figures clearly show clinical agent information input by a clinician contrary to what applicant states. Furthermore, in some embodiments the clinician may compile the genetic profile whereby the clinician would clearly input the information.

Applicant repeats the same arguments for the rejection of independent claims 18 and 35, which have been addressed as stated above.

Applicant further alleges that dependent claims 11, 28, and 45 are allowable over the Hogan reference because the amendment wherein the list of one or more polymorphism values is dynamically accumulated.

Applicant's allegations are not found persuasive as the clinician may compile the genomic profile, which reads on dynamically accumulating the list of polymorphism values. Furthermore, the list may be obtained from public and private databases, which upon obtaining the profile information, the list is clearly being dynamically accumulated.

The rejection of claims under 35 USC 103 is being maintained and reiterated below:

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 10-16, 18-24, 27-33, 35-41, and 44-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over HOGAN (US 2002/0110823, filed 7/11/00) in view of USAMI et al. (J. Human Genetics (1999) vol. 44/5, pp. 304-307).

HOGAN teaches a method of preventing adverse reactions to operative and post-operative drugs (agents) comprising receiving/obtaining data about clinical agents, and whether the clinical agents are associated with one or more genes (para's 117 and 136), as in claims 1, 18, and 34. HOGAN teaches comparing genetic test result values for multiple genes to polymorphism values associated with adverse reactions; i.e. risks associated with atypical clinical events (para's 186, 115, 129, and 136-147), and teaches that "agent information" may include dosage and other PK/PD parameters

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(para 129), as in claims 1, 2, 4, 5, 11, 12, 14, 16, 18, 19, 21, 22, 28, 29, 31, 33, 35, 36, 38, 39, , 45, 46, 48, 50. HOGAN teaches outputting information about the atypical clinical event associated with the polymorphism value(s) such that a "clinical action" may be initiated (para's 190-191), as recited in claims 6, 13, 23, 30, 40, and 47. HOGAN teaches that clinical agent and genetic information may be stored and communicated via various computerized applications, including electronic medical records (para's 186 and 188), thus making obvious a computer system and computer readable medium for performing his analysis, as recited in claims 3, 10, 20, 27, 37, and 44.

Although HOGAN teaches that his agents cause adverse clinical reactions (para 126), he does not specifically teach that his output is a "warning" that an agent should not be administered.

USAMI teaches that where a person is known to have a polymorphism indicating an adverse reaction to a clinical agent, a warning is initiated that the person should not be administered the agent (p. 306).

It would have been obvious to one of ordinary skill in the art to have initiated a warning in the method, system and medium of HOGAN that an agent should not be administered, as taught by USAMI, where the motivation would have been to save lives and prevent adverse reactions to the agent, as taught by both HOGAN (para's 126 and 194) and USAMI (pp. 306-307: Discussion).

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

Lee A. Claw
Patent Examiner
9/4/07